

JAN 29 2002

K013639

14.0 510(k) Safety Summary

A. Name of Device

Trade Name: Thermage ThermaCool TC System (Model TC)
Common Name: Electrosurgical Unit and Accessories
Classification Name: Device, Electrosurgical Cutting and Coagulation and Accessories (21 CFR 878.4400)
Contact Person: Pamela M. Buckman, RN, MS
Sr. Director of Regulatory/Clinical Affairs

B. Predicate Devices

ThermaCool TC System (including coolant canister and footswitch):

Device	Premarket Notification
Thermage ThermaCool IIA System	K013034, Cleared 10/4/01
Thermage ThermaCool II System	K003183, Cleared 12/8/00
Thermage ThermaCool System	K000944, Cleared 7/19/00

Other ThermaCool TC System Accessories (return pad, coupling fluid and skin marking paper):

Accessory	Predicate	Premarket Notification
Return Pad	Nikomed Electrosurgical Grounding Pad	K000079, Cleared 2/4/00
Coupling Fluid	Cadwell Lectron II	K933804, Cleared 3/22/94
Skin Marking Paper	Skin Marker	Class I, Exempt (878.4660)

C. Device Description

The Thermage ThermaCool TC System consists of the following components:

- RF Generator
- Coolant Control Center
- Coolant Canister
- Handpiece Assembly (consisting of Handpiece and Treatment Tip)
- Accessory cables and tubing
- Optional footswitch component
- Accessories: coupling fluid, return pad and skin marking paper

The Handpiece Assembly and Coolant Control Center connect to the RF Generator.

D. Indicated Use

The Thermage ThermaCool TC System is indicated for use in Dermatologic and General Surgical procedures for electrocoagulation and hemostasis.

E. Technical characteristics

The technological characteristics of the Thermage ThermaCool TC System are substantially equivalent to those of the Thermage ThermaCool IIA System, ThermaCool II System, and ThermaCool System.

F. Summary

By virtue of design, principle of operation, materials and intended use, the Thermage ThermaCool TC System is substantially equivalent to devices currently cleared for marketing in the United States.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 29 2002

Ms. Pamela M. Buckman, RN, MS
Sr. Director of Regulatory/Clinical Affairs
Thermage
4058 Point Eden Way
Hayward, California 94545-3721

Re: K013639

Trade Name: Thermage Thermacool TC System
Regulation Number: 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: November 2, 2002
Received: November 5, 2001

Dear Ms. Buckman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

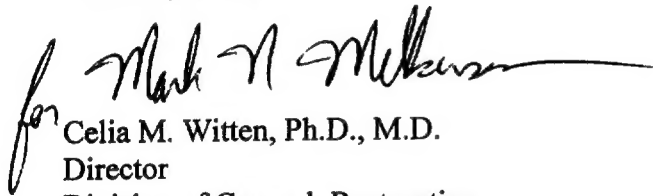
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Page 2 – Ms. Pamela Buckman

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director

Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) NUMBER (IF KNOWN): K013639

DEVICE NAME: Thermage ThermaCool TC System (Model TC)

INDICATIONS FOR USE:

The Thermage ThermaCool TC System (Model TC) is indicated for use in Dermatologic and General Surgical procedures for electrocoagulation and hemostasis.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ☒

(Per 21 CFR 801.109)

OR

Over-The-Counter-Use ☐

for Mark A. Millam
(Division Sign-Off)

Division of General, Restorative
and Neurological Devices

Thermage ThermaCool TC System 510(k)

510(k) Number K013639